Remarks

Status and Disposition of Claims

This Amendment is responsive to the Office Action mailed August 28, 2009. In the Action, the Office considered claims 1-6, 10-13, 15, and 16, claims 7-9 and 14 having been withdrawn from consideration as directed to a non-elected invention.

With this Amendment, Applicants amend claim 10 to even further clarify what is being claimed, cancel claim 13, and add new claims 17-20. Thus, with this amendment, claims 1-6, 10-13, and 15-20 remain pending and under consideration. Applicants allow claims 7-9 and 14 to remain pending, as they are subject to possible rejoinder.

Priority under 35 U.S.C. § 119

Applicants also note with thanks that the Office has acknowledged Applicants' foreign priority claim and receipt of all priority documents.

Information Disclosure Statements

Applicants note with thanks that the Office indicates consideration of the documents listed in an Information Disclosure Statement filed July 6, 2009.

However, Applicants note that a Supplemental Information Disclosure statement was filed July 14, 2006, but that the Examiner's consideration of this Statement does not appear to be reflected in the record. Applicants respectfully request that the Examiner indicate such consideration in the next official communication.

Restriction Requirement

The Office withdraws claims 7-9 and 14, as drawn to a non-elected invention. Applicants allow claims 7-9 and 14 to remain pending, as they are subject to possible rejoinder.

Specification Objections

The Office Action objects to the Abstract for exceeding 150 words. This amendment addresses this objection by reducing the length of the Abstract to fewer than 150 words.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office Action rejects claims 1-6, 10-13, 15, and 16 under 35 U.S.C. § 112, first paragraph, as allegedly not enabled. The Action notes that the claims are enabled for the range shown in the Examples and Tables, but not for the larger ranges claimed. The Action notes that these claims allegedly encompass a standard deviation of 0, which "would be very improbable if not impossible to achieve." The Action asserts that the claimed ranges of standard deviation encompass values that are larger than the pore diameter and membrane thickness and, thus, are not enabled. Applicants respectfully submit that it appears that the Office misinterprets the claims, and respectfully disagree with the rejection for the reasons that follow.

The Action asks, "[H]ow can one have a standard deviation of 0.6 for a diameter of 0.1?" Applicants respectfully submit that the Office's hypothetical question, and assertion that the standard deviation encompasses values that are larger than the pore diameter and/or membrane thickness, are based on a misinterpretation of the claim. Applicants note that claim 1 (the only independent claim) recites "an average pore diameter D (μm) of $0.1 \leq D \leq 50$, a standard deviation σd (μm) of pore diameter of $0 \leq \sigma d/D \leq 0.6$." The standard deviation (σd) recited in the claim is not set forth as an actual standard deviation, but rather as a fraction or a percentage of the diameter (D): $0 \leq \sigma d/D \leq 0.6$. Thus, according to this equation, the *ratio* of the standard deviation to the diameter is from 0 to 0.6. Based on this equation, for a diameter of 0.1, the standard deviation would be from 0 to 0.06. Thus, the Office's assertion that the claims somehow cover a standard deviation of 0.6 for a diameter of 0.1 is based on a misinterpretation of the claims.

The Action also asserts that the claims encompass a standard deviation of 0, which in the Examiner's opinion, would be "very improbable if not impossible to achieve." Again, Applicants respectfully point out that the value of "0" that the Action refers to is not a standard deviation value *per se* but rather the ratio of the standard deviation to the diameter. While it

appears that the Office's concern is based on a misinterpretation of the claims, and further, though the Office has set forth no reasonable basis to challenge Applicants' assertion as to the enablement of the claimed invention, Applicants will address the merits of this rejection.

Theoretically, the values of σd/D and σt/T (claim 3) can be very close to 0. The standard deviation of a pore diameter is a value obtained by averaging each standard deviation of pore diameters from the nine image ranges as described in the specification (see paragraph [0056]), and thus there is no reason to doubt that the standard deviation of pore diameters is very close to, if not exactly, 0. The average membrane thickness, T, is calculated from the sections near the 9 points, at intervals of 50 μm, as described in the specification (see paragraph [0057]), and thus there is no reason to doubt that the standard deviation of pore diameters is very close to, if not exactly, 0. If the Office maintains this rejection, Applicants respectfully note that the Office bears the burden of explaining the rejection (other than Examiner opinion that a claimed value is "very improbable if not impossible"), or to state that it doubts the objective truth of statements made by Applicants in the specification.

Still further, if this rejection is maintained, Applicants respectfully submit that it cannot be made final, as it appears to have been based entirely on a misinterpretation of the claims. That is, the Office set forth no reasonable basis for supporting its assertions, and to the extent that any arguments were presented, it is clear that they were based on misinterpretations. Thus, the Office has failed to make a first rejection based on the present claim scope, and thus, any further rejection under 35 U.S.C. § 112, first paragraph, should not be made final.

Applicants respectfully submit that the pending claims satisfy the requirements of 35 U.S.C. § 112, first paragraph, and respectfully request withdrawal of the rejection.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Office Action rejects claims 10-13 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Action asserts that the claims are incomplete because it is not clear to what the "capability of removing leukocytes between 1.0 and 3.5" refers.

In response, Applicants respectfully note that the "capability of removing leukocytes" is expressly defined in the specification in paragraph [0045] of the original specification.

> [0045]
>
> The capability of the first filter to remove leukocytes is between 1.0 and 3.5, preferably between 1.3 and 3.3, and more preferably between 1.5 and 3.0, for 450 cm3 of the hemocyte suspension to be treated.
>
> In the case of the first filter, the "capability of removing leukocytes" is obtained using the following formula (1) based on the concentrations of leukocytes in a hemocyte suspension before and after filtration obtained when 450 cm3 of the hemocyte suspension to be treated is passed through the first filter.
>
> Capability of removing leukocytes = -log (a leukocyte concentration in the hemocyte suspension after filtration/a leukocyte concentration in the hemocyte suspension before filtration) ... (1)

In view of this explicit definition, Applicants respectfully submit that the claims are clear and definite in view of the specification. However, in an effort to advance prosecution, Applicants have amended claim 10 to expressly recite the definition set forth in the specification.

In view of the foregoing remarks and amendments, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Claim Rejections – 35 U.S.C. § 103

The Office Action rejects claims 1-6 under 35 U.S.C. § 103 as allegedly obvious over JP 2003-149096, to Tanaka et al. in view of U.S. Application Publication No. 2003/0150808, to Morikawa et al., as evidenced by U.S. Application Publication No. 2006/0097361, to Tanaka et al. (hereinafter '361) and U.S. Patent No. 4,992,485, to Koo et al. The Action further rejects claims 10-13 over Tanaka et al., Morikawa et al., and U.S. Patent No. 6,645,388, to Sheikh-Ali et al. The Action further rejects claims 15 and 16 over U.S. Patent No. 5,665,596, to Mussi et al., in view of Tanaka et al. in view of Morikawa et al., as evidence by JP 2001-157574, to Shimomura et al.

Applicants respectfully disagree with the rejections for the reasons that follow.

Initially, Applicants note that, as discussed above, the Office Action misinterprets the claims. To the extent that the Office maintains this rejection, Applicants respectfully request that the Office explain how the features of the claims are found in the cited art.

Turning to the substance of the rejection, Applicants respectfully submit that the pore membrane of the present invention differs from, and is nonobvious over, the honeycombed structure membrane of Tanaka et al. The porous membrane of the present invention has a characteristic structure in which a part of the supporting porous membrane penetrates into the adjacent supporting membrane. When the supporting porous membrane is a nonwoven fabric, for example, a part of the fibers that constitute nonwoven fabric adheres to or penetrates into the honeycombed structure membrane, which unifies the honeycombed membrane with the fibers. This structure exhibits noticeably advantageous effects in tightly combining a porous membrane with a supporting porous membrane that are not to easily separated from each other. In addition, the structure of the porous membrane of the present invention is particularly suitable for effective co-culture of cells because the cells introduced into the supporting porous membrane, e.g., a nonwoven fabric, can easily arrive at or make contact with the honeycombed structure membrane by moving along the nonwoven fabric.

Recognizing that this feature is absent from Tanaka et al., the Office Action relies on Morikawa et al. for the use of casting membranes on a porous support to improve performance and enhance durability for filter operations. Applicants respectfully submit, however, that a person skilled in the art would not combine the teachings of Tanaka et al. with those of Morikawa et al., at least because the publications are in different technical fields. The technical field of Tanaka et al. is blood filtration, as disclosed in the section of "Technical Field of the Invention" of Tanaka et al. On the other hand, the subject matter of Morikawa et al. is a separation membrane for use in purification of sewage. Applicants respectfully submit that the technical fields of both inventions are so different that one of ordinary skill in the art would never have combined these teachings as the Office suggests.

Furthermore, even if one of ordinary skill in the art had thought of combining the teaching of Tanaka et al. with that of Morikawa et al., he or she would never have arrived at the composite porous membrane of the present invention. The production method of Morikawa et

al. requires at least two steps: (1) applying stock solution of the porous resin layer onto one side or both sides of a porous substrate (polyester nonwoven fabric in Example 1) and then (2) immersing it into nonsolvent, as disclosed in Example 1. However, it is practically impossible to perform such a process unless the viscosity of the stock solution is sufficiently high because it is very difficult to retain the stock solution on or in the porous substrate until the process proceeds to step (2). The viscosity of the stock solution disclosed in Example 1 of Morikawa et al. (the solid content concentration of 18.5 weight%) cannot be accurately determined because the molecular weight of PVDF is not disclosed; however, it is clear from the description in Comparative Example 2 that it has a low fluidity and a high viscosity such that the applied stock solution can hardly be immersed into the inside of nonwoven fabric. Comparative Example 2 of Morikawa et al. discloses that when the stock solution was applied onto nonwoven fabric with a density of 0.90 g/cm3, no composite layer was observed on the finally obtained separation membrane, but only a porous resin layer was placed on the substrate, and the porous resin layer was found to be detached from the porous substrate after a permeation test. These disclosures suggest that the stock solution has a low fluidity and a high viscosity and the stock solution applied on nonwoven fabric can hardly be immersed into the inside of the nonwoven fabric. That is, the method of Morikawa et al. can be carried out only when the viscosity of the stock solution is high enough to be applied onto the surface of a porous substrate (nonwoven fabric) (or high enough to be adequately immersed into the porous substrate).

On the other hand, the method of Tanaka et al. uses, as disclosed in Example 1, a diluted stock solution with a polymer concentration of 0.1 to 2 weight% (chloroform as solvent). The stock solution with such a diluted concentration has a fluidity identical to water, so the movement or loss of the stock solution must be prevented until it forms a membrane structure by casting it on the liquid-repellent substrate, such as glass (glass plate), agarose gel, or mica. However, such a stock solution with a high fluidity cannot be cast on the surface of a porous substrate such as nonwoven fabric because the stock solution permeates into or flows out of the nonwoven fabric. Comparative Example 3 of this application corresponds to the case in which the stock solution was cast on nonwoven fabric so as not to flow out the stock solution. Electron micrograph observation for the product after the removal of chloroform revealed that a proper composite porous membrane was not formed by using this procedure. The blockage of the pores

occurred because chloroform dried up with the stock solution retained inside of nonwoven fabric, and the break of porous membrane was frequently observed near the surface of nonwoven fabric due to many undulations on the surface of nonwoven fabric.

Therefore, even if one were to combine the production methods disclosed by Tanaka et al. and Morikawa et al., one of ordinary skill in the art would not have arrived at the present invention to produce a composite layer by forming a honeycombed membrane on the surface of a porous substrate.

Applicants respectfully submit that the additional teachings of the '361, Koo et al., Sheikh-Ali et al., Mussi et al., and Shimomura et al. all fail to supply any teaching that would suggest the combination of the disparate teachings of Tanaka et al. and Morikawa et al., and further fail to supply any teaching that would cause a person skilled in the art modify Tanaka et al. and Morikawa et al. so as to arrive at the present invention.

In view of the foregoing, Applicants respectfully submit that a person skilled in the art would not have combined the disparate teachings of Tanaka et al. and Morikawa et al. as suggested by the Office, and even if the teachings were combined, the present invention would not result. Applicants respectfully request withdrawal of the rejection.

Conclusion

In view of the foregoing remarks and amendments, Applicants respectfully request withdrawal of the rejections of record and allowance of the claims. If the Examiner has any questions or wishes to discuss this application further, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

The Patent and Trademark Office is hereby authorized to charge Deposit Account No. 19-0089 any fee necessary to ensure consideration of this paper.

Respectfully Submitted,
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